APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DATED AND DECIDED JUNE 8, 2001

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

00-1272

APOTEX USA, INC.,

Plaintiff-Appellant,

v.

MERCK & CO., INC.,

Defendant-Appellee.

DECIDED: June 8, 2001

Before LOURIE, CLEVENGER, and LINN, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Apotex USA, Inc. appeals from the decision of the United States District Court for the Northern District of Illinois granting Merck & Co., Inc.'s motion for summary judgment that the claims of U.S. Patents 5,573,780 and 5,690,962 are invalid under 35 U.S.C. § 102(g). *Apotex Corp. v. Merck & Co.*, No. 96-C-7375, 2000 WL 97,582 (N.D. Ill. Jan. 25, 2000) ("*Apotex I*"). Because the district court did not err in granting summary judgment that the '780 and '962 patents are invalid under 35 U.S.C. § 102(g), we affirm.

Appendix A

BACKGROUND

Apotex is the assignee of the '780 and '962 patents, which relate to a process for making a stable solid formulation of enalapril sodium for use in the treatment of high blood pressure. *Apotex I* [2000 WL 97582,] at *1. Claim 1 of the '780 patent, which is representative of the claims at issue, reads as follows:

> 1. A process of manufacture of a pharmaceutical solid composition comprising enalapril sodium, which process comprises the steps of:
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> i) a) mixing enalapril maleate with an alkaline sodium compound and at least one other excipient, adding water sufficient to moisten, and mixing to achieve a wet mass, or
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> b) mixing enalapril maleate with at least one excipient other than an alkaline sodium compound, adding a solution of an alkaline sodium compound in water, sufficient to moisten and mixing to achieve a wet mass; thereby to achieve a reaction without converting the enalapril maleate to a clear solution of enalapril sodium and maleic acid sodium salt in water,
>
> ii) drying the wet mass, and
>
> iii) further processing the dried material into tablets.

'780 patent, col. 5, l. 34 to col. 6, l. 15. The claims of the '962 patent, which is a continuation of the application that led to the '780 patent, are identical to those found in the '780 patent except that they are not restricted to tablet form, but rather encompass any solid pharmaceutical dosage form of enalapril sodium. '962 patent, col. 5, l. 22 to col. 6, l. 11. This distinction is not material to the resolution of this appeal.

Merck manufactures enalapril sodium under the trade name VASOTEC®, and has been continuously manufacturing and commercially selling VASOTEC® tablets since 1983. *Apotex I* at *7. Merck owns both U.S. and Canadian patents covering the enalapril sodium compound, but does not own a patent covering its process of manufacturing VASOTEC®. *Id.* at *1. However, in 1992, Merck disclosed the ingredients utilized in its VASOTEC® manufacturing process in a Canadian product monograph, and more than 30,000 copies of the monograph were distributed in 1993 alone. *Id.* at *7. Merck also disclosed the ingredients used in manufacturing RENITEC® (the trademark used for its enalapril sodium product sold in various foreign countries) in the 1988 edition of the Dictionnaire Vidal, a French pharmaceutical dictionary. *Id.*

In 1991, Merck and its Canadian subsidiary, Merck Frosst Canada, Inc., sued Apotex's Canadian affiliate, Apotex Canada, for infringement of Merck's Canadian patent covering the enalapril sodium compound. *Id.* at *1. During the 1994 trial ("the Canadian trial"), Brian McLeod, Merck's then-vice president of marketing, performed a step-by-step narration of a videotape demonstrating Merck's process of manufacturing VASOTEC®. *Id.* Within days of hearing this

testimony, Dr. Bernard Sherman, an Apotex official, allegedly conceived the patented process at issue. *Id.*

Apotex filed the present action against Merck, alleging that Merck's process of manufacturing VASOTEC® infringes all of the claims of both the '780 and '962 patents. *Id.* Both parties filed cross-motions for summary judgment on the issue of infringement, and Merck cross-moved for summary judgment of invalidity under § 102(g). *Id.* The district court granted Apotex's motion for summary judgment of infringement, but also granted Merck's cross-motion for summary judgment of invalidity because it found that Merck invented the process claimed in the '780 and '962 patents within the United States before Apotex, and did not abandon, suppress, or conceal that invention within the meaning of § 102(g). *Id.* at *9.

Apotex thereafter filed a motion asking the court to reconsider its grant of summary judgment of invalidity, which the district court denied. *Apotex Corp. v. Merck & Co.*, No. 96-C-7375, 2000 WL 656,670 (N.D. Ill. Mar. 17, 2000). Apotex appeals from the district court's grant of summary judgment of invalidity. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1) (1994).

DISCUSSION

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FED. R.

CIV. P. 56(c). For purposes of the motion, "[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). We review a district court's grant of a motion for summary judgment *de novo*. *Ethicon Endo-Surgery, Inc. v. United States Surgical Corp.*, 149 F.3d 1309, 1315, 47 USPQ2d 1272, 1275 (Fed. Cir. 1998).

Apotex argues that the district court improperly invalidated the '780 and '962 patents because Merck failed to prove by clear and convincing evidence that it did not suppress or conceal the patented process. Apotex contends that proof of invalidity under § 102(g) requires Merck to prove that it did not suppress or conceal the process of manufacturing VASOTEC® tablets based on its activities within the United States, and that Merck's foreign disclosures therefore cannot be used to satisfy its burden of proof. Apotex also contends that, in any event, Merck's foreign disclosures fail to prove that it did not suppress or conceal the process because nothing in the testimony from the Canadian trial, the product monograph, or the French dictionary disclosed the use of water, the occurrence of an acid-base chemical reaction between enalapril maleate and sodium bicarbonate, or the resultant enalapril sodium product. Finally, Apotex argues that the evidence demonstrates that Merck in fact suppressed or concealed its invention by failing to file a patent application on the process, by submitting misleading information in its New Drug Application ("NDA") that only disclosed the starting ingredients used to make VASOTEC®, and by preventing the details of its process from circulating outside of the company.

Merck responds that § 102(g) only requires proof that the prior invention was made in the United States, and that evidence of lack of suppression or concealment can be proven by both foreign and domestic activities. Merck further argues that it did not suppress or conceal the process because it used it commercially, disclosed it in open court directly to its competitor, and published the ingredients used to make VASOTEC® tablets in both the product monograph and the French dictionary. Merck also argues that the submissions it made with respect to its NDA were proper and in any event could not constitute suppression or concealment because it was the Food and Drug Administration that never made those submissions public. Finally, Merck contends that the process was not suppressed or concealed because it was obvious and Dr. Sherman admitted that VASOTEC® tablets could be reverse-engineered to reveal the details of the process.

Section 102(g) operates to ensure that a patent is awarded only to the "first" inventor in law. In addition to governing priority determinations in interference proceedings in the United States Patent and Trademark Office, § 102(g) may be asserted as a basis for invalidating a patent in defense to an infringement suit. *New Idea Farm Equip. Corp. v. Sperry Corp.*, 916 F.2d 1561, 1566, 16 USPQ2d 1424, 1428 (Fed. Cir. 1990) (citation omitted). That section provides in relevant part that: "A person shall be entitled to a patent unless . . . before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it." 35 U.S.C.A. § 102(g) (West Supp. 2000). Therefore, if a patentee's invention has been made by another, prior inventor who has not abandoned, suppressed, or concealed the invention,

§ 102(g) will invalidate that patent. *New Idea*, 916 F.2d at 1566, 16 USPQ2d at 1428.

Apotex does not dispute that Merck invented the patented process in the United States well before Dr. Sherman's alleged date of conception. Apotex also concedes that Merck did not abandon its process of manufacturing VASOTEC® tablets as shown by its continuous commercial use of the process since 1983. The sole issue on appeal, therefore, is whether Merck "suppressed" or "concealed" the process within the meaning of § 102(g). Whether suppression or concealment has occurred is a question of law, which we review *de novo*. *Brokaw v. Vogel*, 429 F.2d 476, 480, 166 USPQ 428, 431 (CCPA 1970).

As an initial matter, we disagree with Apotex's interpretation of § 102(g) as requiring proof negating suppression or concealment to arise from activities occurring within the United States. The plain language of § 102(g) clearly requires that the prior invention be made "in this country." However, in light of the grammatical structure of § 102(g), it would be a strained reading of that provision to interpret the language "in this country" to also modify the requirement that the prior invention was "not . . . abandoned, suppressed, or concealed." A more reasonable interpretation is that it only modifies the antecedent verb "made," but not the "abandoned, suppressed, or concealed" clause that follows it. Had Congress intended the phrase "in this country" to modify "abandoned, suppressed, or concealed," it would have inserted language to that effect.

Indeed, if there were any doubt, the legislative history of § 102(g) demonstrates that Congress contemplated that

precise modification, as it applied to another clause in § 102(g), and failed to adopt it. An earlier version of that provision considered in the House read as follows:

> [B]efore the applicant's invention thereof the invention was in fact made **in this country** by another who had not abandoned it and who was using reasonable diligence **in this country** in reducing it to practice or had reduced it to practice.

H.R. 3760, 82nd Cong. (1951) (emphasis added). The fact that the drafters found it desirable to emphasize that the language "in this country" applies to "using reasonable diligence" as well as to the word "made" supports the conclusion that it only modifies the verb that precedes it and not any subordinate clause that follows it. Accordingly, based upon the plain language of § 102(g) and the relevant legislative history of that provision, we conclude that the language "in this country" only applies to the country where "the invention was made," and that proof negating suppression or concealment is not limited to activities occurring within the United States.

We next turn to an issue that has not been squarely addressed by this court in considering suppression or concealment as negating prior invention in a defense to an infringement suit under § 102(g) — the burdens of proof governing such a determination. Section 282 of the Patent Act provides that "[a] patent shall be presumed valid." 35 U.S.C.A. § 282 (West Supp. 2000). In order to overcome the presumption of validity, the party challenging a patent must prove facts supporting a determination of invalidity by clear

and convincing evidence. *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360, 220 USPQ 763, 770 (Fed. Cir. 1984). Section 282 applies with full force to a § 102(g) defense, and thus a party asserting invalidity under § 102(g) must prove facts by clear and convincing evidence establishing a prior invention that was not abandoned, suppressed, or concealed. *See Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co.*, 973 F.2d 911, 915, 23 USPQ2d 1921, 1924 (Fed. Cir. 1992).

In *Young v. Dworkin*, one of our predecessor courts set forth the relevant burdens of proof governing a determination whether a prior invention was suppressed or concealed, in the context of an interference between co-pending applications, as follows:

> The sole remaining question is whether the board correctly held that junior party-appellant suppressed or concealed his invention within the meaning of 35 U.S.C. § 102(g). Here, the senior party-appellee bears the burden of proof by a preponderance of the evidence, notwithstanding junior party-appellant's burden on the issue of priority of invention which he has sustained.

Young v. Dworkin, 489 F.2d 1277, 1279, 180 USPQ 388, 390 (CCPA 1974) (citing *Gallagher v. Smith*, 206 F.2d 939, 99 USPQ 132 (CCPA 1953)). Thus, under § 102(g) interference law involving co-pending applications, once the first party to invent has established priority of invention, the second party to conceive and reduce the invention to practice has the burden of proving that the first party suppressed or

concealed the invention. In such an interference, the first party to invent does not bear any burden of proof regarding suppression or concealment once it has established an earlier date of invention.

A § 102(g) prior invention defense is governed by the identical "suppressed or concealed" language applicable to priority determinations in interference proceedings. 35 U.S.C. § 102(g). We must therefore interpret the § 102(g) defense provision consistently with established interference law. However, infringement actions implicating a § 102(g) defense differ from interferences in that a patent has been granted on the invention at issue, and therefore the presumption of validity under § 282 applies.[1] Because the patentee (analogous to the second-to-invent in the interference context) has the benefit of the presumption of validity, that party should only be held to bear a burden of

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1. Generally speaking, the presumption of validity does not apply to patents involved in interference proceedings, and thus the invalidity of a patent involved in an interference under § 102(g) need only be proven by preponderant evidence. *See Bruning v. Hirose*, 161 F.3d 681, 686, 48 USPQ2d 1934, 1938 (Fed. Cir. 1998) (holding that, in an interference involving a patent issued from an application that was co-pending with the interfering application, the appropriate standard of proof for validity challenges is the preponderance of the evidence standard because the presumption of validity is inapplicable). However, the presumption may effectively be implicated in the case of a priority contest between an issued patent and an application that was filed after the issuance of the patent. In such a situation, the junior party must establish priority of invention by clear and convincing evidence. *Price v. Symsek*, 988 F.2d 1187, 1194, 26 USPQ2d 1031, 1036 (Fed. Cir. 1993). Such a factual scenario is not before us.

producing evidence indicating that the prior inventor may have suppressed or concealed the invention once the challenger (analogous to the first-to-invent in the interference context) has established prior invention by clear and convincing evidence. That burden bears a rough similarity to placing the burden of proving suppression or concealment on the second-to-invent under interference law, but at the same time is appropriately limited to one of production, not persuasion, giving due regard to the presumption of validity.

We therefore interpret § 102(g) as requiring that once a challenger of a patent has proven by clear and convincing evidence that "the invention was made in this country by another inventor," 35 U.S.C. § 102(g), the burden of production shifts to the patentee to produce evidence sufficient to create a genuine issue of material fact as to whether the prior inventor has suppressed or concealed the invention. However, in accordance with the statutory presumption in 35 U.S.C. § 282, the ultimate burden of persuasion remains with the party challenging the validity of the patent. *See Innovative Scuba Concepts, Inc. v. Feder Indus., Inc.*, 26 F.3d 1112, 1115, 31 USPQ2d 1132, 1134 (Fed. Cir. 1994) ("While a patentee may have the burden of going forward with rebuttal evidence once a challenger presented a *prima facie* case of invalidity, the presumption of validity remains intact and the ultimate burden of proving invalidity remains with the challenger throughout the litigation." (citing *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376, 231 USPQ 81, 87 (Fed. Cir. 1986))). Once the patentee has satisfied its burden of production, the party alleging invalidity under § 102(g) must rebut any alleged suppression or concealment with clear and convincing evidence to the contrary.

Appendix A

Our case law distinguishes between two types of suppression or concealment. The first is implicated in a situation in which an inventor actively suppresses or conceals his invention from the public. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1567, 39 USPQ2d 1895, 1901 (Fed. Cir. 1996) (citing *Kendall v. Winsor*, 62 U.S. (21 How.) 322, 328 (1858)). The second involves a legal inference of suppression or concealment based upon an unreasonable delay in filing a patent application.[2] *Peeler v. Miller*, 535 F.2d 647, 655, 190 USPQ 117, 122 (1976) (holding that a four-year delay in filing a patent application after the invention was perfected was unreasonably long); *Shindelar v. Holdeman*, 628 F.2d 1337, 1342, 207 USPQ 112, 116 (1980) (finding suppression or concealment because no reasonable explanation was given for the two-year and five-month delay between reduction to practice and the filing of a patent application). The latter type is involved here.

Although a prior inventor implicated in a § 102(g) infringement defense may not have filed a patent application, in contrast to an interference contestant, that party's delay in otherwise bringing the knowledge of the invention to the public may nevertheless raise a similar inference of suppression or concealment. *See Int'l Glass Co. v. United States*, 408 F.2d 395, 403, 159 USPQ 434, 441 (Ct. Cl. 1969)

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2. A subset of the category of "inferred" suppression or concealment arises in a situation in which the first inventor is "spurred" into filing a patent application by another application, *Mason v. Hepburn*, 13 App.D.C. 86 (D.C. Cir. 1898), or by the commercial activity of another, *Woofter v. Carlson*, 367 F.2d 436, 445-446, 151 USPQ 407, 416 (CCPA 1967). This case does not involve "spurring."

(holding that the prior invention of a process did not invalidate a patent on the same process under § 102(g) because the prior inventor did nothing to make the invention known to the public). Even though there is no explicit disclosure requirement in § 102(g), the spirit and policy of the patent laws encourage an inventor to take steps to ensure that "the public has gained knowledge of the invention which will insure its preservation in the public domain" or else run the risk of being dominated by the patent of another. *Palmer v. Dudzik*, 481 F.2d 1377, 1387, 178 USPQ 608, 616 (CCPA 1973); *see also Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1446, 1453, 223 USPQ 603, 607, 614 (Fed. Cir. 1984) (defining § 102 "prior art" to be "technology already available to the public," and stating that "secret prior art" may not be used to invalidate a patent under § 102(g)); *Oddzon Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1402, 43 USPQ2d 1641, 1645 (Fed. Cir. 1997) ("[W]hen the possessor of secret prior art (art that has been abandoned, suppressed, or concealed) that predates the critical date is faced with a later-filed patent, the later-filed patent should not be invalidated in the face of this 'prior' art, which has not been made available to the public. Thus, prior, but non-public, inventors yield to later inventors who utilize the patent system."). Absent a satisfactory explanation for the delay or the presence of other mitigating facts, a prior invention will therefore be deemed suppressed or concealed within the meaning of § 102(g) "if, within a reasonable time after completion, no steps are taken to make the invention publicly known." *Int'l Glass*, 408 F.2d at 403, 161 USPQ at 441.

In the case at hand, we find that Apotex has satisfied its burden of producing evidence sufficient to create a genuine

issue of material fact that Merck suppressed or concealed its process of manufacturing enalapril sodium tablets. We emphasize at the outset that although § 102(g) prior art must be somehow made available to the public in order to defeat another patent, a § 102(g) prior inventor is under no obligation to file a patent application. *Checkpoint Sys., Inc. v. United States Int'l Trade Comm'n*, 54 F.3d 756, 763, 35 USPQ2d 1042, 1048 (Fed. Cir. 1995). Thus, while Merck's failure to file a patent application may be relevant to a determination whether it suppressed or concealed its process, especially if there were evidence that such failure was based on a decision to retain the invention as a trade secret, that failure alone does not satisfy the patentee's burden of producing evidence sufficient to create a genuine issue of material fact of suppression or concealment. *See E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1437, 7 USPQ2d 1129, 1135 (Fed. Cir. 1988) (explaining that a patent application need not be filed on an invention for it to be considered § 102(g) prior art as long as the invention is found not to have been abandoned, suppressed, or concealed).

However, Apotex did allege that Merck failed to make its invention publicly known. Merck perfected its process and began commercially using the process to manufacture VASOTEC® tablets no later than 1983. Although Merck argues that its process was disclosed to the public because its VASOTEC® tablets could have been reverse-engineered, that argument is based on the admissions of Dr. Sherman, who drew upon the information provided in Merck's subsequent disclosures to determine the details of the

process.[3] Thus, it appears that Merck took no steps to make the invention publicly known for nearly five years, when it first published the ingredients used in its process in the 1988 edition of the Dictionnaire Vidal. We find that such a delay raises an inference that Merck suppressed or concealed its invention. Accordingly, because Apotex has successfully discharged its burden of going forward with evidence creating a genuine issue of material fact of suppression or concealment, the burden shifts to Merck to rebut that showing by clear and convincing evidence to the contrary.

We conclude that Merck has succeeded in rebutting the inference of suppression or concealment created by its period of inactivity by clear and convincing evidence. In *Paulik v. Rizkalla*, we stated the rule that "the first inventor will not be barred from relying on later, resumed activity antedating an opponent's entry into the field, merely because the work done before the delay was sufficient to amount to a reduction to practice." 760 F.2d 1270, 1275, 226 USPQ 224, 228 (Fed. Cir. 1985) (holding that the inference of suppression or concealment from a four-year delay between reduction to practice and the filing of a patent application was overcome by the first inventor's resumption of activity before the

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3. It is worth noting that if it were clear that Merck's process could be reverse-engineered by one of ordinary skill through an inspection of VASOTEC® tablets, Apotex could not benefit from the inference of suppression or concealment because Merck could not be said to have delayed in making the benefits of its invention known to the public. *See Palmer*, 481 F.2d at 1386-87 (stating that a commercial use of an invention will preclude a finding of suppression or concealment only when such use enables the public to learn of the invention).

second inventor's date of conception). Thus, even though Merck may have suppressed or concealed the process for a period of time after it reduced it to practice in 1983, as long as it "resumed activity" (*i.e.*, made the benefits of its invention known to the public) before Apotex's entry into the field, it cannot be deemed to have suppressed or concealed the invention within the meaning of § 102(g).

Merck made several disclosures following its period of suppression or concealment that made the invention publicly known, all of which took place before Apotex's entry into the field (here, Dr. Sherman's alleged conception in April of 1994). First, Merck disclosed the ingredients used in manufacturing VASOTEC® tablets in the 1988 edition of the Dictionnaire Vidal. It also widely distributed the product monograph in Canada from October 1992 through 1994, which similarly disclosed the ingredients it used in its manufacturing process. Merck also provided a step-by-step description of the process through the testimony given by Brian McLeod at the Canadian trial on March 28, 1994.

Apotex argues that these disclosures inadequately described Merck's process of manufacturing VASOTEC® tablets, and therefore that the public never received the benefit of the invention. However, Dr. Sherman admitted both in his deposition in this case and in his 1994 Statement of Facts prepared for the Canadian trial that his inspection of the VASOTEC® tablets that Merck sold commercially revealed that they were made using a wet granulation process. He also admitted that, after learning of the disclosed starting ingredients from the Canadian product monograph (which included sodium bicarbonate), it "immediately occurred" to

him and was "obvious to any knowledgeable formulator or chemist" that the final enalapril sodium product in the VASOTEC® tablets was the result of an acid-base chemical reaction between enalapril maleate and sodium bicarbonate in water. Merck's various disclosures, in conjunction with Apotex's admissions, therefore clearly and convincingly prove that Merck made the knowledge of its invention available to the public, thereby satisfying its burden of rebutting Apotex's evidence of suppression or concealment.

Moreover, Apotex's argument that Merck suppressed or concealed the process by submitting misleading information to the FDA in 1983 is irrelevant because any suppression that was implicated was overcome by Merck's subsequent activity. We therefore conclude that the district court did not err in granting summary judgment that the '780 and '962 patents are invalid under § 102(g).

We have considered Apotex's remaining arguments and find them to be unpersuasive.

CONCLUSION

Because the district court did not err in granting summary judgment that the '780 and '962 patents are invalid under 35 U.S.C. § 102(g), we

AFFIRM.

APPENDIX B — MEMORANDUM OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION DATED AND DECIDED JANUARY 20, 2000 AND DOCKETED JANUARY 25, 2000

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS,
EASTERN DIVISION

Case No. 96 C 7375

APOTEX CORP.,

Plaintiff,

v.

MERCK & CO., INC.,

Defendant.

January 20, 2000, Decided
January 25, 2000, Docketed

MEMORANDUM OPINION AND ORDER

MATTHEW F. KENNELLY, District Judge:

In this patent infringement suit, Apotex Corporation accuses Merck & Co. of infringing two patents held by Apotex, U.S. Patent No. 5,573,780 and U.S. Patent No. 5,690,962. The parties filed cross motions for summary judgment on the infringement issue, and in addition, Merck

has filed a motion for summary judgment that the patents are invalid. We address each motion below.

FACTUAL BACKGROUND

The Patent and Trademark Office issued Patent No. 5,573,780 (the '780 Patent), entitled "Stable Solid Formulation of Enalapril Salt and Process for Preparation," to Dr. Bernard Sherman on November 12, 1996. The PTO issued Patent No. 5,690,962 (the '962 Patent), which is a continuation of the '780 Patent and therefore shares the same title, on November 25, 1997. Sherman assigned his rights in both patents to Apotex. The patents cover a process for making a pharmaceutical compound for use in the treatment of high blood pressure. In the simplest of terms, the patented process involves mixing the active ingredient, enalapril maleate, with an alkaline sodium compound and at least one other inactive ingredient or "excipient,"[1] adding water to the mix, drying the mix and processing the dried mix into tablets. The claimed novelty of the invention was that it produced a stable compound "without requiring the steps of suspending the enalapril maleate in water, adding the alkaline sodium compound and mixing until the reaction is complete and a clear solution is formed." U.S. Patent No. 5,573,780, col. 1, line 65 – col. 2, line 4; U.S. Patent No. 5,690,962, col. 1, line 65 – col. 2, line 4. In this lawsuit, Apotex accuses Merck of infringing all of the claims of its two patents.

Before we turn to the merits of the parties' summary judgment motions, a bit of history is in order. This is not the

1. An excipient is an inert substance added to a mixture to give it bulk or some other desirable characteristic.

first time these parties have sparred over their respective rights to patents involving the drug enalapril maleate. In 1991, Merck and its Canadian subsidiary, Merck Frosst Canada, Inc., sued Apotex's Canadian affiliate, Apotex Canada, for infringement of Merck Frosst's patent that claims the drug substance enalapril. The record does not permit the Court to determine whether the Canadian patent Merck sought to enforce in the Canadian litigation covers the same process Apotex attacks in this lawsuit. Nor is it clear what process or product of Apotex's Merck was accusing of infringement in that litigation, though it clearly was not the process covered in the '780 and '962 Patents because Sherman had not yet conceived of that process. But Merck's process for making VASOTEC — the accused process here — was definitely at issue in the Canadian litigation because as part of its case, Merck played a videotape of one of its employees demonstrating the process, and Merck's then vice president of marketing, Brian McLeod, took the stand to narrate the tape and to give a play-by-play of the process.

The outcome of the Canadian litigation is not important for our purposes. However, the trial is relevant here because it set the stage for this lawsuit: Sherman apparently conceived of the patented process within days after McLeod testified about Merck's process.

DISCUSSION

1. Applicable Legal Standard

The Federal Circuit has stated that summary judgment is as appropriate in a patent case as it is in any other case.

See, e.g., *Avia Group International, Inc. v. L.A. Gear California, Inc.*, 853 F.2d 1557, 1561 (Fed. Cir. 1988). Thus, summary judgment is appropriate when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(c). In determining whether there is a genuine issue of fact, we view the evidence and draw all reasonable inferences in favor of the party opposing the motion. See *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986); *Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 795 (Fed. Cir. 1990). Where cross motions are filed, we apply the same standard, adopting a dual perspective. See *Stimsonite Corp. v. Nightline Markers, Inc.*, 33 F. Supp. 2d 703, 705 (N.D. Ill. 1999).

2. The Parties' Cross Motions on Infringement

Patent infringement occurs if a person makes, uses, offers to sell or sells a patented invention within the United States during the term of the patent. 35 U.S.C. § 271(a). Infringement exists if every limitation of the patent claims asserted to be infringed (in this case, all of the claims) is found in the accused process. *SmithKline Diagnostics, Inc. v. Helena Laboratories Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988). To determine whether infringement has occurred, we must first define as a matter of law the meaning and scope of each patent claim at issue; then we compare the accused process against the properly construed claims to see whether the claim limitations are met either literally or by a substantial equivalent. See *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 387-91, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996); *Stimsonite*, 33 F. Supp. 2d at 706-07 (citing *Renishaw PLC*

v. Marposs Societa 'per Azioni, 158 F.3d 1243, 1247-48 (Fed. Cir. 1998)).

To determine the meaning and scope of the patent claims, we look first to the intrinsic evidence — namely, the claims, the specification or written description, and the prosecution history. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). If one of ordinary skill in the art can interpret the intrinsic evidence unambiguously, the court looks no further. *Id.* at 1583.

The principal dispute about claim interpretation in this case is whether Apotex's process requires a "complete" reaction of the active ingredient, enalapril maleate; in other words, whether the patents are limited to those processes in which all of the enalapril maleate is converted to enalapril sodium. Merck argues that the patents require a complete reaction; Apotex argues that they do not. To resolve the dispute, we look first to the claims themselves. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999) (claim construction begins with the language of the claims). The '780 Patent claims:

> 1. A process of manufacture of a pharmaceutical solid composition comprising enalapril sodium, which process comprises the steps of:
>
> (i)(a) mixing enalapril maleate with an alkaline sodium compound and at least one other excipient, adding water sufficient to moisten, and mixing to achieve a wet mass, or

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(b) mixing enalapril maleate with at least one excipient other than an alkaline sodium compound, adding a solution of alkaline sodium compound in water, sufficient to moisten and mixing to achieve a wet mass; thereby to achieve a reaction without converting the enalapril maleate to a clear solution of enalapril sodium and maleic acid sodium salt in water.

(ii) drying the wet mass, and

(iii) further processing the dried material into tablets.

2. A process as in claim 1 wherein the alkaline sodium compound is selected from the group consisting of sodium hydroxide, sodium carbonate and sodium bicarbonate.

3. A process as in claim 1 or 2 wherein the excipient is lactose.

4. A process as in any of claims 1 to 3 which further comprises addition of a lubricant.

5. A process as in claim 4 wherein the lubricant is a metal stearate.

6. A process as in claim 5 wherein the metal stearate is magnesium stearate.

7. A process as in any of claims 1 to 6 which further comprises the addition of a disintegrant.

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8. A process as in claim 7 wherein the disintegrant is starch.

9. A pharmaceutical solid composition comprising enalapril sodium salt when made by a process according to any of claims 1 to 8. U.S. Patent No. 5,573,780 at col. 5, line 34 – col. 6, line 34.

The '962 Patent's claims are identical in all respects relevant to this lawsuit. *See* U.S. Patent No. 5,690,962, col. 5, line 22 – col. 6, line 27.

Nothing in the claim language calls for a complete reaction. Claim 1(i)(b) — the only claim to specifically mention the reaction — states that the goal of the patented process is "to achieve a reaction without converting the enalapril maleate to a clear solution of enalapril sodium and maleic acid sodium salt in water." U.S. Patent No. 5,573,780, col. 6, lines 10–12. See also U.S. Patent No. 5,690,962, col. 6, lines 5–7 ("to achieve a reaction without converting the enalapril maleate to a clear solution of enalapril sodium and maleic acid in water."). Neither this claim nor any of the other claims speak in terms of a "complete" reaction of the enalapril maleate. Similarly, the specification emphasizes that the reaction is designed to produce stability. See U.S. Patent No. 5,573,780, col. 1, lines 23–67; U.S. Patent No. 5,690,962, col. 1, 24 – col. 2, line 4. If a process that otherwise reads on the claims achieves stability with a reaction that is less than complete, that process would infringe the patents.

The language on which Merck relies to support its claim construction appears in the specification: "It has been found

that so long as the amount of water used is sufficient to render the mass very moist, the acid-base reaction will occur rapidly and will be complete or essentially complete before the drying of the mass in the subsequent drying process is completed." U.S. Patent No. 5,573,780, col. 3, lines 38–42; U.S. Patent No. 5,690,962, col. 3, lines 30–34 (emphasis added). Merck argues that "essentially complete" means "complete." This interpretation is unreasonable because it would require the Court to read "essentially complete" out of the equation. The more reasonable interpretation of that phrase is that it means "virtually complete," that is, "mostly complete but not entirely complete."

Having construed the pertinent claim language, we compare the patented process with the process accused of infringement. During the Canadian infringement litigation, Merck's witness Brian McLeod testified in detail about the process Merck uses to make VASOTEC. McLeod testified that the active ingredient, enalapril maleate, is mixed with "a carrier," "a stabilizer," "a binder" and a "disintegrant." Transcript of McLeod Testimony at 123, 125. Then that mixture is mixed in a "wet granulation"[2] with water to get "a damp mass" or "a wet mass." *Id.* at 127. He clarified that by "damp" or "wet mass" he meant that the mixture was "damp but not gooey." *Id.* He stated that the mass is then spread thinly on trays and placed into a "drying oven" to remove

2. "Wet granulation" is a term used to describe a processing method in pharmaceutical manufacturing in which a solvent (usually water) is used to wet, to the consistency of damp snow or brown sugar, the ingredient being mixed in making a medicinal tablet. Merck's Mem. in Support of Its Summary Judgment Motion on Invalidity, at 3–4.

the moisture. *Id.* at 128. He stated that after the mixture is dried, a lubricant is added — he specifically identified the lubricant as magnesium stearate. *Id.* He stated that the mixture is then formed into tablets. *Id.* at 128-29. Finally, he testified that the goal of the process was to make the tablets in a way that "ensured that each tablet will deliver the exact amount of active ingredient." *Id.* at 125. Thus the only apparent difference between Merck's process, as described by McLeod, and Apotex's process, as described in the claims, is that Merck's process uses "a carrier," "a stabilizer," and "a binder" whereas Apotex's process uses "an alkaline sodium compound and at least one other excipient." If we dig a little deeper, we see that these are really different names for the same things. Interestingly, Apotex's specification uses one of these same words. See U.S. Patent No. 5,573,780, col. 1, 15–18; U.S. Patent No. 5,690,962, col. 1, lines 15–18 ("In order to manufacture pharmaceutical tablets, it is necessary to mix the active ingredient with inactive ingredients which may serve as binders . . . .") (emphasis added). And Merck's product monograph states that, in addition to the active ingredient enalapril maleate, the mix contains the following inactive ingredients or excipients: "lactose, magnesium stearate [the lubricant], sodium bicarbonate and starch [the disintegrant]." Product Monograph for VASOTEC and VASOTEC I.V., at 15 (Oct. 19, 1992). Claim 2 of the patents makes clear that sodium bicarbonate is "an alkaline sodium compound," and Claim 3 of the patents makes clear that lactose is an excipient. U.S. Patent No. 5,573,780, col. 6, lines 16–21; U.S. Patent No. 5,690, 962, col. 6, lines 12–16. Thus, Merck's process reads on all of the claims of the '780 and '962 Patents.

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Merck argues that its process does not infringe the patented process because its process "is not 'wet' enough to meet the 'wet mass' limitation" in Claim 1. Merck's Mem. at 12. The argument is undercut substantially by the fact that McLeod described Merck's "wet mass" the same way Sherman described Apotex's "wet mass." But it fails for another reason as well. The claim language is silent as to how much water goes into the mix; the claims do not specify how much water is "sufficient to moisten" or how much water is necessary to "achieve a wet mass." The specification does, however, includes 3 examples of how to achieve the intended result. See U.S. Patent No. 5,573,780, col. 3, line 65 — col. 5, line 32; U.S. Patent No. 5,690,962, col. 3, line 57 – col. 5, line 20. In the first example, the desired "wet mass" was achieved by dissolving 12.2g of sodium hydroxide (an alkaline sodium compound) in 400g of water and then adding that solution to a mixture containing 50g of enalapril maleate and 1660g of lactose monohydrate powder (the other excipient). *Id.* at col. 4, lines 5–31. In the second example, the desired "wet mass" was achieved by dissolving 32.3g of sodium carbonate in 400g of water and then adding that solution to a mixture containing 100g of enalapril maleate, 1600g of lactose monohydrate powder and 5g of a colouring agent. *Id.* at col. 4, lines 35–67. In the third example, the desired "wet mass" was achieved by adding 400g of water to a mixture containing 50g of enalapril maleate, 25.6g of sodium bicarbonate and 1650g of lactose monohydrate powder. *Id.* at col. 5, lines 1–32. Merck's process uses a much lower proportion of water to the enalapril maleate compound than is specified in the specification's examples. The wet granulation in Merck's process is generated by mixing about 12% water by weight as compared with the dry ingredients,

whereas, according to Merck, if we did the math in the above examples, we would find that Apotex's process uses at least 23% water by weight. Based on this fact, Merck argues that its process cannot literally infringe the patents. We disagree.

Merck's noninfringement argument would require the Court to read a limitation from the written description into the claims, something we are not permitted to do under the law. *See Vitronics*, 90 F.3d at 1582. It is true that if a particular term in need of definition is used but not defined in the claims, we may look to the specification for such a definition. *See Renishaw*, 158 F.3d at 1248. But even if we were to find that the terms "sufficient to moisten" and "wet mass" — used but not defined in Claim 1 — open the door for us to look at the specification for elucidation of those phrases, the specification clearly states that it is not intended to confine the patents' scope. Certainly the examples given clarify what amount of water may be "sufficient to moisten" and what combination of ingredients may create a "wet mass." The specification expressly states, however, that the examples disclosed are "intended to be illustrative but not limiting of the invention." U.S. Patent No. 5,573,780, col. 3, lines 65–67; U.S. Patent No. 5,690,962, col. 3, lines 54–56. The examples are just that — examples; they do not foreclose the possibility that other proportions would also achieve the intended result. Thus, the fact that Merck uses different amounts of water or different amounts of enalapril maleate or different amounts of any of the other ingredients is of little consequence.

There are no material issues of fact on the infringement issue; the parties' respective processes are what they are.

Based on the facts, as described above, the Court finds that Merck's process literally infringes Apotex's patents, that Apotex is entitled to judgment as a matter of law and that Merck is not. Of course, invalidity is a defense to infringement. *See* 35 U.S.C. § 282 (alleged infringer who can show that the patent asserted against him or her is invalid cannot be liable for infringement); *Ever-Wear, Inc. v. Wieboldt Stores, Inc.*, 427 F.2d 373, 376 (7th Cir. 1970) (only valid patents may be infringed). So we must still consider Merck's motion for summary judgment that the patents are invalid.

2.[sic] Merck's Motion for Summary Judgment that Apotex's Patents are Invalid

This is not the first time Merck has asked the Court to hold Apotex's patents invalid. Merck previously sought summary judgment on the same issue, though on different grounds. In its earlier motion, Merck argued that it was entitled to summary judgment under 35 U.S.C. § 102(f) because Sherman derived the subject matter of the patents in suit from Merck's process (in other words, Sherman was not the original inventor; Merck was). Subsection (f) provides that a person shall be entitled to a patent unless "he did not himself invent the subject matter sought to be patented." It is a derivation provision, which provides that one may not obtain a patent on that which is obtained — through public information or through communications with the prior inventor — from someone else whose possession of the subject matter is inherently "prior." *See Oddzon Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1401 (Fed. Cir. 1997). According to Magistrate Judge Ashman, to whom the case had been referred, both parties agreed "that Merck was the

first to conceive the subject matter claimed in the '780 Patent" and that the only question for him to decide was whether Merck's conception was communicated to Dr. Sherman "in a manner that would enable one of ordinary skill in the art to make stable enalapril tablets." Report and Recommendation at 9. Judge Ashman recommended that the Court deny summary judgment because he found an issue of fact as to whether Dr. Sherman concluded on his own that Merck used a wet granulation process to make its tablets (as Sherman claimed) or whether Sherman learned about the process through some communication from Merck (as Merck claimed). *Id.* at 11. The parties did not object to Judge Ashman's recommendation, and Judge Marovich, to whom this case was previously assigned, accepted it and denied summary judgment. This time around, Merck is attempting to avoid the fact issues identified by Judge Ashman by arguing that it is entitled to summary judgment under 35 U.S.C. § 102(g), which does not require that the second inventor actually know about the prior invention. *See E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1437 (Fed. Cir.), *cert. denied*, 488 U.S. 986, 102 L. Ed. 2d 572, 109 S. Ct. 542 (1988).

Before deciding whether Apotex's patents are invalid under 35 U.S.C. § 102(g), we must quickly address Apotex's argument that this section "requires acts in the United States" and does not apply because Merck's public disclosure of its process took place in Canada. Section 102(g) provides as follows:

> [a] person shall be entitled to a patent unless . . . before the applicant's invention thereof the

> invention was made in this country by another who had not abandoned, suppressed, or concealed it.

By its plain language, the statute requires only that the process is invented in the United States, not that the process be employed or disclosed in the United States after being invented. *See also Paulik v. Rizkalla*, 760 F.2d 1270, 1278 (Fed. Cir. 1985) (Rich, J., concurring). Judge Rich, who was intimately involved in drafting § 102(g), explained that one of the earlier versions of the statute required more of the inventor's activities to occur in the United States; specifically, it required that the prior invention be "made in this country by another who had not abandoned it and who was using reasonable diligence in this country in reducing it to practice. . . ." *Paulik*, 760 F.2d at 1278 (Rich, J., concurring). That language was taken out in favor of the current version, which requires only that the invention be made in this country and not abandoned, suppressed or concealed — in any country. *Id.* The undisputed record evidence shows that Merck's scientists invented the accused process and reduced it to practice at Merck's lab in West Point, Pennsylvania. In short, section 102(g) does apply, and we now consider the consequences of that application.

A patent is presumed to be valid. 35 U.S.C. § 282. The party challenging the patent's validity must show, by clear and convincing evidence, that the patent is invalid. *Checkpoint Systems, Inc. v. United States International Trade Commission*, 54 F.3d 756, 761 (Fed. Cir. 1995); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1375 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947, 94 L. Ed. 2d 792, 107 S. Ct. 1606 (1987). Thus, Merck must prove by

clear and convincing evidence that Apotex's patents are invalid. Because it is asserting invalidity under 35 U.S.C. § 102(g), Merck must prove by clear and convincing evidence that: (1) Merck invented its process within the United States before Sherman invented his process; and (2) Merck neither abandoned, suppressed nor concealed its invention.

The parties agree that Merck invented the allegedly infringing process long before Sherman conceived of the idea. Apotex admits that Merck's scientists developed the process at its West Point, Pennsylvania facility in the early 1980s. Apotex further admits that Sherman conceived of the idea for the patented process some time after March 30, 1994 and before April 19, 1994 and that his invention was first reduced to practice on April 19 or within a few days thereafter. Thus the first element of Merck's defense is satisfied. Moreover, the evidence does not suggest, and Apotex does not contend, that Merck abandoned the process; indeed, the evidence establishes that Merck has been using its process continuously since at least 1983. Thus, under 35 U.S.C. § 102(g), the only question for the Court is whether Merck suppressed or concealed its invention at the time Sherman allegedly conceived of the process.

The purpose of our patent law is to "advance the useful arts" and "technological innovation"; "to encourage innovation and its fruits." *Paulik*, 760 F.2d at 1276. "As implemented by the patent statute, the grant of the right to exclude [others from making a particular product or using a particular process] carries the obligation to disclose the workings of the invention, thereby adding to the store of knowledge without diminishing the patent-supported

incentive to innovate." *Id.* Section 102(g) fits into this scheme by encouraging "prompt public disclosure of an invention by penalizing unexcused delay or failure of a first inventor to share the 'benefit of the knowledge of [the] invention' with the public after the invention has been completed." *Checkpoint Systems*, 54 F.3d at 761 (quoting *Paulik*, 760 F.2d at 1280 (Rich, J., concurring)). Priority under this section goes to "the 'first' inventor in law, regardless of fact." *Paulik*, 760 F.2d at 1281 (Rich, J., concurring). To determine priority, we ask not only who first conceived of the invention, but also "whether the facts as to what was or was not done lead to the legal conclusion of 'suppressed, or concealed.' " *Id.* at 1280. See also *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1567 (Fed. Cir. 1996). Suppression or concealment may be intentional, as when the prior inventor "designedly, and with the view of applying it indefinitely and exclusively for his own profit, withholds his invention from the public." *Paulik*, 760 F.2d at 1273 (quoting *Kendall v. Winsor*, 62 U.S. (21 How.) 322, 328, 16 L. Ed. 165 (1858)). Or suppression or concealment may be inferred from the facts of the particular case, where for example, an inventor delays "too long" in filing a patent application. *Fujikawa*, 93 F.3d at 1565 (citing *Paulik*, 760 F.2d at 1273).

In *Paulik*, the Federal Circuit inventoried the decisions involving suppression or concealment under section 102(g). After briefly discussing the cases, the court summarized the law as follows:

> The decisions applying section 102(g) balanced the law and policy favoring the first person to make an invention, against equitable

> considerations when more than one person had made the same invention: in each case where the court deprived the de facto first inventor of the right to the patent, the second inventor had entered the field during a period of either inactivity or deliberate concealment by the first inventor.

760 F.2d at 1275.

This case simply does not fit that mold. Certainly Apotex cannot accuse Merck of inactivity; by 1994, when Sherman conceived of the patented process, Merck had been continuously using its process to make VASOTEC tablets and it had been selling its product in the commercial markets for more than a decade. In 1993 alone Merck had more than $150 million in VASOTEC sales.

Nor do the facts of this case suggest that Merck deliberately suppressed or concealed its invention. The test for suppression or concealment under § 102(g) is whether within a reasonable time after completion of the invention, the prior inventor took steps to make its invention publicly known. *Levi Strauss & Co. v. Golden Trade, S.r.L.*, 1995 U.S. Dist. LEXIS 4899, Nos. 92 Civ. 1667 (RPP), 90 Civ. 6291 (RPP), 90 Civ. 6292 (RPP), 1995 WL 710822, at *18 (S.D.N.Y. Dec. 1, 1995) (citing *International Glass Co. v. United States*, 187 Ct. Cl. 376, 408 F.2d 395, 403 (Ct. Cl. 1969)). *See also Checkpoint Systems*, 54 F.3d at 763 (no suppression or concealment if public promptly received the benefit of knowledge of first inventor's product). "Possible steps [to make the invention publicly known] include filing a patent application, describing the invention in a publicly

disseminated document, and using the invention publicly." *Levi Strauss*, 1995 WL 710822, at *18. Merck prepared and distributed widely its product monograph, which describes its VASOTEC tablets and gives a list of the ingredients used to make the tablets, as well as the chemical name, the structural formula, the molecular weight and the composition. Merck distributed more than 30,000 copies of the monograph in 1993 alone. Merck also described its product in the Dictionnaire Vidal, a French language pharmaceutical dictionary, and it disclosed the process for making VASOTEC tablets at the Canadian infringement trial — significantly, without seeking any kind of a protective order or other means of limiting disclosure of the process to the general public. Merck also used its invention publicly, selling the fruits of the invention in mass quantities in the commercial markets. Taken together, these facts clearly and convincingly establish that Merck did not intentionally suppress or conceal its invention.

In opposition to Merck's motion, Apotex has argued that Merck suppressed and concealed its invention to keep others from breaking into the enalapril maleate tablet market. Yet, Apotex offers no evidence to back up this claim. Apotex can point only to the fact that Merck never filed a patent application, and this alone is not sufficient to support a finding of deliberate suppression or concealment. *See E.I. du Pont*, 849 F.2d at 1437 (failure to file patent application does not by itself constitute suppression or concealment).

Apotex argues that the way in which Merck disclosed its process was not sufficient to show a person of ordinary skill in the art how to duplicate the process. The Court

disagrees. As described above, Brian McLeod's testimony and the accompanying videotape explained the process in detail. And to the extent McLeod failed to specifically name any of the ingredients used in the process, Merck's product monograph and the Dictionnaire Vidal were available to fill in any blanks. Apotex also argues that Merck's evidence of disclosure does not satisfy § 102(g) because the disclosure was not made in a single written publication. But § 102(g) does not require disclosure at all, let alone disclosure in a particular form. It requires, as we have already noted, that the invention not be abandoned, suppressed or concealed. Written public disclosure is just one possible way to demonstrate that an invention has neither been abandoned, suppressed or concealed.

Finally, Apotex argues that Merck lied to the Food & Drug Administration in its new drug application (NDA) for Tablets VASORIL (Enalapril Maleate, MSD) dated September 15, 1983. Apotex argues that in section 7 of the NDA, Merck listed the starting ingredients for these tablets when it should have listed the ingredients in the final composition of the tablets. Merck did this, according to Apotex, to hide the fact that a reaction occurs in the tableting process because, if Merck had disclosed the end product's ingredients, the FDA "would have been alerted to the fact that a chemical reaction had occurred and [the FDA reviewer] would have probed Merck as to the tableting process." Apotex's Mem. in Opposition to Merck's Summary Judgment Motion, p. 15. Even if we accept Apotex's allegations as true, we fail to see how this bears on the issue of suppression or concealment. To the extent Apotex is implying that in 1983 Merck was hiding the fact that its process involved reacting

enalapril maleate to form a more stable enalapril sodium compound, that time frame is irrelevant. The relevant time frame for purposes of § 102(g) is when the later inventor conceives of his invention — in this case, some time between March 30, 1994 and April 19, 1994. By that time, Merck had fully disclosed the ingredients and the process. Plus, even Apotex's witnesses agreed that any chemist who knew the ingredients and knew that the process involved adding water to the mix would automatically know that a reaction of the enalapril maleate occurred. Dr. Richard McKeag, a scientist who worked with Dr. Sherman at Apotex Canada, testified that "it was so simple that it was obvious; any chemist would know that, if you added bicarbonate or carbonate to a solution containing enalapril maleate, you would get the formation of the salt. You would get a chemical reaction to form a salt." McKeag Deposition Transcript, at 41. He also testified that "if you take sodium bicarbonate and put it into water and you have enalapril maleate in the same solution, it will react virtually spontaneously and irreversibly to form a new compound, to form enalapril sodium and disodium maleate." *Id.* at 46. Finally, he testified that "any chemist who looks at enalapril maleate would automatically assume its going to react with three moles of sodium bicarbonate . . . if they are placed together in solution or in slurry or whatever, anything wet." *Id.* at 47. In short, what Apotex characterizes as "rank suppression and concealment" would not have fooled anyone — or at least anyone with a fundamental knowledge of chemistry.

Under the standards articulated above, Merck is both the first inventor in fact and the first inventor in law, and principles of equity, when viewed against the facts of this

particular case, require the Court to give priority to Merck. Accordingly, the Court finds that Apotex's patents are invalid under 35 U.S.C. § 102(g).

CONCLUSION

For the reasons explained above, the Court finds that Merck's process for making VASOTEC enalapril maleate tablets literally infringes U.S. Patent No. 5,573,780 and U.S. Patent No. 5,690,962. But the Court further finds that Merck has a defense to the literal infringement — namely invalidity under 35 U.S.C. § 102(g) — because Merck invented its process for making VASOTEC in the United States before Sherman invented the process covered in the '780 and '962 Patents and neither abandoned, suppressed nor concealed that process. Accordingly, the Court denies Merck's motion for summary judgment of noninfringement, grants Apotex's motion for summary judgment of infringement and grants Merck's motion for summary judgment that the patents in suit are invalid. Judgment will enter in favor of Merck and against Apotex.

Dated: January 20, 2000

MATTHEW F. KENNELLY
United States District Judge

APPENDIX C — MEMORANDUM OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION DATED AND DECIDED MARCH 17, 2000 AND DOCKETED MARCH 23, 2000

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS,
EASTERN DIVISION

Case No. 96 C 7375

APOTEX CORP.,

Plaintiff,

v.

MERCK & CO., INC.,

Defendant.

March 17, 2000, Decided
March 23, 2000, Docketed

MEMORANDUM OPINION AND ORDER

MATTHEW F. KENNELLY, District Judge:

On January 20, 2000 the Court issued an opinion granting summary judgment to the defendant, Merck & Co. *See Apotex Corp. v. Merck & Co., Inc.*, 2000 U.S. Dist. LEXIS 641, No. 96 C 7375, 2000 WL 97582 (N.D. Ill. Jan. 25, 2000). The Court held that Apotex's '780 and '962 patents are invalid

under 35 U.S.C. § 102(g) because Merck invented the patented process in the United States before Apotex and did not abandon, suppress or conceal its process. Apotex has asked the Court to reconsider this ruling. Familiarity with the Court's January 20 opinion is assumed.

First, Apotex argues that the Court was wrong to consider evidence from the Canadian litigation and wrong to combine disclosures to find that Merck neither suppressed nor concealed its invention. As before, Apotex cites no authority for these propositions. The Court will therefore rely on its earlier analysis: the test for suppression or concealment under § 102(g) is whether within a reasonable time after completion of the invention, the prior inventor took steps to make its invention publicly known. *See Levi Strauss & Co. v. Golden Trade, S.r.L.*, 1995 U.S. Dist. LEXIS 22145, Nos. 92 Civ. 1667 (RPP), 90 Civ. 6291 (RPP), 90 Civ. 6292 (RPP), 1995 WL 710822, at *18 (S.D.N.Y. Dec. 1, 1995) (*citing International Glass Co. v. United States*, 187 Ct. Cl. 376, 408 F.2d 395, 403 (Ct. Cl. 1969)). This section does not limit how an inventor may accomplish this, and we see nothing in the law to preclude us from considering evidence adduced in a foreign country or from considering various disclosures in combination to answer the question. *See E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1436 n.5 (Fed. Cir. 1988) (court considered filing of foreign patent application in concluding that invention was neither suppressed nor concealed); *Application of Hilmer*, 53 C.C.P.A. 1288, 359 F.2d 859, 878 (C.C.P.A. 1966) ("acts in a foreign country are not to defeat the rights of applicants for patents, except as applicants may become involved in priority disputes.") (emphasis added).

Appendix C

Second, Apotex argues that the disclosures on which the Court relied did not disclose a key part of Merck's process: the chemical reaction between the active ingredient enalapril maleate and the sodium bicarbonate. The Court addressed this issue in its January 20 opinion, concluding that anyone with a working knowledge of chemistry would know that if enalapril maleate and sodium bicarbonate are present, a reaction occurs — Apotex's own witnesses, including Dr. Bernard Sherman, admitted as much.

Apotex argues that the Court asked the wrong question; rather than asking whether a reaction was disclosed because of the presence of these ingredients, we should have asked whether the evidence disclosed that these ingredients were actually mixed together in the process. Apotex argues that the Canadian litigation evidence, even when read in combination with the product monograph and Dictionnaire Vidal entry, did not disclose the presence of sodium bicarbonate in the initial mix; rather they disclosed the presence of sodium bicarbonate in the end product that results when the process is complete. Thus, according to Apotex, the fact that the product monograph lists sodium bicarbonate would not allow a chemist — or anyone else — to conclude that a chemical reaction between these two ingredients necessarily occurred. At best, Apotex argues, whether the product monograph lists the chemical make-up of Merck's tablets or the ingredients that go into the process to make the tablets is a question of fact that should have precluded summary judgment.

Contrary to Apotex's assertion, the record evidence, including the new evidence presented with Apotex's motion

to reconsider, does not support a finding that Merck concealed or suppressed the presence of sodium bicarbonate in its process. Apotex cites the declarations of Dr. Bernard Sherman, Dr. Stanley Scheindlin and Jens T. Carstensen to support its argument that the monograph concealed or suppressed the existence of sodium bicarbonate in the process. First, this substantially misreads Dr. Sherman's declaration. Sherman did not say that the monograph could be read to say that sodium bicarbonate was present in the final tablet rather than the mixing process; he actually said that interpreting the product monograph this way made absolutely no sense: "As can be seen, [the product monograph] stated that 'each tablet contains non-medicinal ingredients including . . . sodium bicarbonate.' I knew this could not be true since my 1990 experiments established that a tablet with enalapril maleate and sodium bicarbonate was unacceptably unstable." Sherman Declaration, P11 (attached as Exhibit A to Apotex's Mem. of Law Opposing Merck's Motion for Summary Judgment under 35 U.S.C. § 102(g)). In light of Sherman's admission that a stable tablet could not contain enalapril maleate and sodium bicarbonate, it is difficult to imagine that he ever believed sodium bicarbonate was present in the end product and not in the mixing process. With the public disclosure in 1994 that the process involved wet granulation, such a belief would have been totally unfounded.

Nor do the declarations of Scheindlin and Carstensen reveal an issue of fact on this score. Carstensen said that he believed pharmaceutical professionals would read the monograph to mean that the listed ingredients (including the sodium bicarbonate) were present in the tablets; Scheindlin

stated that he believed health professionals and the general public could read the monograph to mean that the listed ingredients (including the sodium bicarbonate) were present in the tablets. Even if we accept these statements as true, they do not create an issue of fact on concealment or suppression, *see Wolverine World Wide, Inc. v. Nike, Inc.*, 38 F.3d 1192, 1199 n.5 (Fed. Cir. 1994) ("contradictory litigation-induced pronouncements are insufficient to raise a genuine issue of material fact"), especially in light of the fact that Sherman's own declaration totally undermines the argument that the monograph concealed or suppressed anything.

Apotex argues that the Court's interpretation of the monograph as disclosing the list of ingredients that go into the mix "sub silentio overrules Magistrate Judge Ashman's findings of a genuine issue of fact, previously adopted by the Court." Mem. In Support of Motion for Reconsideration, p. 6. This argument misreads Judge Ashman's ruling: he did not find an issue of fact as to whether the product monograph disclosed the ingredients in the process or the ingredients in the tablet; rather, he found issues of fact as to whether Sherman discovered that Merck used a wet granulation process from the product monograph or from some other independent source, and as to whether the product monograph would enable one of ordinary skill in the art to conclude that Merck's tablets were made using a wet granulation method. See Report and Recommendation, pp. 10-11. Neither of these issues were material to this Court's analysis because: (1) what Sherman knew when he "invented" his process, though relevant for purposes of 35 U.S.C. § 102(f) (the statutory basis for the motion before Judge Ashman), was immaterial

for purposes of § 102(g); and (2) whether or not the product monograph disclosed the wet granulation method, McLeod clearly disclosed that the process used this method when he testified in the Canadian litigation (Judge Ashman could not consider the Canadian litigation evidence because Sherman said he wasn't there to hear it, which though relevant for purposes of the derivation analysis under § 102(f), is immaterial under § 102(g)).

The record evidence before this Court clearly established that enalapril maleate, sodium bicarbonate and other excipients were combined through wet granulation to make the Vastotec [sic] tablets.

Apotex also argues that a Canadian decision, issued the day after this Court issued its opinion, in an action related to the Canadian litigation discussed in the Court's January 20 opinion, supports its argument that the product monograph lists the ingredients in the tablet, not the ingredients in the mixing process. The new Canadian opinion does not support Apotex's argument: the Canadian court found that Nu-Enalapril, a competitor to Vasotec manufactured by Nu-Pharm, Inc. (another company to which Dr. Bernard Sherman is connected), infringed Vasotec because it contains enalapril maleate. The opinion says nothing about sodium bicarbonate. So the Court is left with the disclosure of the process through McLeod's testimony in the Canadian litigation in 1994, through the product monograph and through the Dictionnaire Vidal entry, plus the fact that Merck has been using the process commercially since at least 1983. The Court remains convinced that these disclosures clearly and convincingly prove Merck neither suppressed nor concealed its invention.

Appendix C

At the hearing on Apotex's motion to reconsider, Merck argued that § 102(g) does not require disclosure of the invention to the public; it simply requires that the invention is neither concealed nor suppressed. The Court quite agrees and tried to make this point clear in its January 20 opinion. *See Apotex Corp.*, 2000 U.S. Dist. LEXIS 641, No. 96 C 7375, 2000 WL 97582, at *8. *See also E.I. DuPont*, 849 F.2d at 1437 ("Nor does § 102(g) contain a 'known to the art' requirement apart from the requirement of no abandonment, suppression or concealment."). Thus, whether Merck made its invention "known to the art" or publicly known is immaterial[1] as long as Merck did not otherwise suppress or conceal its invention. As explained above and in the Court's earlier opinion, it did not.

For these reasons, Apotex's motion for reconsideration is denied, as is Merck's motion to strike Apotex's exhibits. Apotex has until March 31, 2000 to respond to Merck's Bill of Costs.

Dated: March 17, 2000

MATTHEW F. KENNELLY
United States District Judge

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1. Having said that, the Court notes that Apotex's new exhibits demonstrate that at least one member of the public, Joseph Schwartz, professor of pharmaceutics and director of industrial pharmacy research at the University of Sciences in Philadelphia, was present in court when McLeod described the process for making Vasotec. *See* Apotex's Mem. In Support of its Motion for Reconsideration, Exhibit O, pp. 55–56.

APPENDIX D — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DENYING PETITION FOR REHEARING DATED, DECIDED AND FILED AUGUST 2, 2001

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

00-1272

APOTEX USA, INC.,

Plaintiff-Appellant,

v.

MERCK & CO., INC.,

Defendant-Appellee.

August 2, 2001, Decided
August 2, 2001, Filed

DECISION WITHOUT PUBLISHED OPINION

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the APPELLANT, and a response thereto having been invited by the court and filed by the APPELLEE, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

Appendix D

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on August 9, 2001.

Circuit Judge GAJARSA did not participate in the vote.

Dated: August 2, 2001

APPENDIX E — UNITED STATES PATENT NO. 5,573,780

[Omitted here but submitted separately as Lodging]

APPENDIX F — UNITED STATES PATENT NO. 5,690,962

[Omitted here but submitted separately as Lodging]

APPENDIX G — *MERCK & CO., INC. v. APOTEX INC.*, 59 C.P.R. (3d) 133 (1994)

[Omitted here but submitted separately as Lodging]

APPENDIX H — *MERCK & CO. v. NU-PHARM INC.*, 4 C.P.R. (4th) 464 (2000)

[Omitted here but submitted separately as Lodging]

APPENDIX I — DECLARATION OF JENS T. CARSTENSEN DATED JULY 10, 1998

[Omitted here but submitted separately as Lodging]

APPENDIX J — DECLARATION OF STANLEY SCHEINDLIN, D.Sc. DATED JULY 12, 1998

[Omitted here but submitted separately as Lodging]

APPENDIX K — DECLARATION OF DR. BERNARD C. SHERMAN DATED JULY 13, 1998

[Omitted here but submitted separately as Lodging]

APPENDIX L — SUPPLEMENTAL DECLARATION OF DR. BERNARD C. SHERMAN DATED JULY 13, 1998

[Omitted here but submitted separately as Lodging]

APPENDIX M — DECLARATION OF STANLEY SCHEINDLIN, D.Sc. DATED DECEMBER 14, 1999

[Omitted here but submitted separately as Lodging]

APPENDIX N — MEMORANDUM TO ROBERT MONAGHAN FROM WILLIAM HITCHINGS RE ENALAPRIL MALEATE – ITALY DATED MAY 10, 1985

[Omitted here but submitted separately as Lodging]